

Patent Application  
NC 95,996

### **REMARKS / ARGUMENTS**

#### **Election/Restriction**

Claims 15, 16 and 26 through 45 remain in this application. The examiner has required an Election/Restriction between Group I (Claims 15 and 26-35) and Group II (Claims 16 and 36-45). Applicant provisionally elected Group II. Applicant affirms this election. Claims 15 and 26-35 have been withdrawn as being directed to a non-elected invention. Applicants reserve the right to pursue the non-elected claims in a divisional application.

#### **Amendment to Specification**

In the Office Action, the Examiner objected to the disclosure for informalities. The specification has been amended to correct the stated informality. In the specification the paragraph citing and incorporating by reference the parent nonprovisional application has been amended to include a reference to the patent number of the now issued parent patent.

#### **Amendments to Claims**

Claims 16 and 36-45 remain in this application. Claim 36 has been cancelled. Claims 16, and 37 – 45 have been amended. No new matter has been added as a result of the current amendment. Support for the new claims can be found in the specification, claims and drawings of the parent application.

#### **Rejection of Claims under 35 USC 112 second paragraph**

In the present office action, the Examiner rejected Claims 16 and 36-45 under 35 USC 112 second paragraph. Specifically, the Examiner states in Claim 16, it is unclear how the pores

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retain the analyte. In response, applicants have amended Claim 16 to claim how the pores retain the analyte. Additionally, the Examiner states that the preamble does not correlate to the body of the claim. In response, applicants have amended the body of the claim to relate to the preamble and positively recite detection of the analyte. Additionally, the Examiner states that there is insufficient antecedent basis for "the surface" in Claim 16. In response, Applicants have amended Claim 16 to provide antecedent basis. Additionally, Applicants have amended Claim 16 to clarify what is meant by reciting "analyte contacts said membrane surface modifiers". Additionally, Applicants have amended Claim 16 to include a step that removes excess labels. Applicants believe that all of Examiners' rejections to Claim 16 have been overcome by the present amendments and respectfully request reconsideration.

Claim 36 has been cancelled by the present amendment, thereby resolving Examiner's rejections to Claim 36. Claims 37- 40 and 42-45 have been amended to depend from Claim 16. The Examiner has rejected Claim 38 as being vague and indefinite. Applicants have amended Claim 38 to clarify the claim. Claim 43 has been amended to clarify the surface that is modified. Additionally, Applicants have amended Claim 45 to correct a minor error.

Applicants believe the above amendments to the Claims address all of the Examiner's rejections under 35 USC 112 second paragraph, and respectfully request reconsideration. No new matter has been added as a result of the current amendment. Support for the new claims can be found in the specification, claims and drawings of the parent application.

#### Rejection of Claims under 35 USC 102

The Examiner has rejected Claims 16, 36, 37, 44 and 45 under 35 USC 102(e) as being

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anticipated by Sosnowski et al (US 6,051,380) ('380). The Examiner states that:

Sosnowski ('380) et al disclose the detection of analytes (abstract). '380 disclose contacting a sample containing the analyte (test solution) to a device. '380 disclose that the device contains a permeation layer with selective diffusion properties (col. 25, lines 13-15). '380 discloses that this permeation layer should have a pore limit property which inhibits larger binding entities, reactants and analytes from passing through to the micro-electrode surface (col 25, lines 26-33). '380 et al disclose that the permeation layer can be a porous membrane (col. 25, line 45 and col. 27, lines 51-53). '380 disclose that the outer surface of the membrane is derivatized with chemical functional groups (membrane surface modifiers) (col 27, lines 52-53). '380 discloses that these chemical functional groups binds to specific binding entities (col 28) and that these specific binding have affinity for another molecule (col 9). '380 discloses that detection of binding reactions can be achieved by using labeled reporter groups and that that these labels can be conjugated to DNA or antibodies (binding ligands) (col 35, lines 35-41). '380 disclose that th labels can be fluorescent, chemiluminescent and enzymatic (col 35, lines 35-41) '380 disclose using an imaging or scanning detector system to detect labels (col 8). Sosnowski disclose that the ideal pore limit is from 2nm to 10 nm (col 27, lines 37-37) '380 disclose that the pores allow a solvent to pass through (col. 25, lines 21-24).

(Emphasis added)

Applicants respectfully traverse Examiner's arguments. The '380 patent neither teaches nor discloses the present invention. The present invention claims flowing a test solution containing an analyte to and through a semipermeable membrane. The '380 patent teaches

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contacting a solution to a microelectrode device. The permeation layer of the '380 patent has the purpose of overlying the electrode to "separate the attached or tethered oligonucleotides and hybridized target DNA sequences from the highly reactive electrochemical environment generated immediately at the electrode surface" (col 7, lines 41-60). Further the '380 patent does not teach flowing the analytes to and through the membrane. "Analytes or reactants can be transported by free field electrophoresis to any specific microlocation..." (col 7, lines 62-64). Specifically, the '380 patent teaches "a device which electronically delivers reagents and reactants with a minimal use of fluidics" (col 11, lines 36-38). Additionally, the '380 patent discloses "The permeation layer provides spacing between the metal surface and the attachment/binding entity layers and allows solvent molecules, small counter-ions, and electrolysis reaction gases to freely pass to and from the metal surface" (col 22, lines 1-4). The '380 patent does not teach or disclose a flow of test solution to and through a semipermeable membrane, rather, it teaches a test solution in contact with the electrodes, with flow of solvent molecules, small counter ions and gases moving in both directions.

The permeation layer of the '380 patent is clearly and specifically aimed at preventing molecules other than the "solvent" from contacting an electrode where they would be damaged. The permeation layer of the '380 patent is designed to have "selective diffusion properties" for this purpose. That design intention is supported by the definition of "permeation" by the American Society for Testing and Materials (ASTM) under ASTM F739:

Permeation Defined: The process by which a chemical moves through a material on a molecular level. The three step process includes: Absorption: Chemical is absorbed into the outer surface of a material. Diffusion: Chemical then diffuses through the material on

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a molecular level. Desorption: Chemical emerges as a vapor on the inside surface of the material. Permeation Rate is expressed as micrograms per square centimeter per minute (ie:  $\mu\text{g}/\text{cm}^2/\text{min}$ ).

Sosnowski ('380) does not teach a membrane designed specifically to separate molecules from solvent using solvent flow (as opposed to diffusion), where the solvent is free to pass through and exit the membrane (as opposed to making contact with a solid electrode on the other side).

Applicants respectfully suggest that the '380 patent therefore neither teaches nor discloses the present invention, and respectfully request reconsideration.

#### Rejection of Claims under 35 USC 103

The Examiner has rejected Claims 38 and 40-42 under 35 USC 103(a) as being unpatentable over Sosnowski et al in view of Butler (US 5,137,634) and in further view of Van Damme et al (US 6,225,131). Applicant believes it has removed the rejection based on the Sosnowski reference above, thus removing this rejection also. Claims 38 and 40-42 depend from Claim 16, making them allowable if Claim 16 is allowable.

The Examiner has rejected claims 39 and 43 under 35 USC 103(a) as being unpatentable over Sosnowski et al in view of Lee et al (US 6,180,418). Applicant believes it has removed the rejection based on the Sosnowski reference above, thus removing this rejection also. Claims 39 and 43 depend from Claim 16, making them allowable if Claim 16 is allowable.

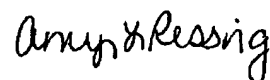
#### Conclusion

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Applicants believe the present amendment is fully responsive to each of the Examiner's objections and rejections. Applicants respectfully request reconsideration and a timely Notice of Allowance be issued in this case. In the furtherance of compact prosecution, if a personal or telephone interview would help expedite matters, the Examiner is requested to contact Amy Ressing at 202-404-1558.

Kindly charge any additional fees due, or credit overpayment of fees, to Deposit Account No. 50-0281.

Respectfully submitted,



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